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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/468,610      | 06/06/1995  | SIMON C. BURTON      | 010055-134          | 5415             |

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BURNS DOANE SWECKER & MATHIS L L P  
POST OFFICE BOX 1404  
ALEXANDRIA, VA 22313-1404

EXAMINER

WEBER, JON P

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/05/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

08/468,610

Applicant(s)

BURTON ET AL.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-23,55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-23,55 and 56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

***Continued Prosecution Application***

The request filed on 23 December 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/468610 is acceptable and a CPA has been established. An action on the CPA follows. Claims 1-5, 7-23, 55 and 56 have been presented for examination.

***Previous Office Action***

The Office action of 31 December 2002 was prepared without knowledge of the CPA filing of 23 December 2002. Accordingly the Office action of 31 December 2002 is hereby vacated.

***Terminal Disclaimer***

The terminal disclaimer filed on 23 December 2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 5,652,348 has been reviewed and is accepted. The terminal disclaimer has been recorded. The Double Patenting rejection is hereby withdrawn in view of the Terminal Disclaimer.

***Claim Rejections - 35 USC § 112***

Claims 55-56 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is argued that new matter is not present. Support for thiol and hydroxyl groups is alleged at least at page 24, lines 5-10. It is argued that this shows that these groups are reactive groups on the ligand. It is urged that these groups are ionizable groups within the meaning of the disclosure.

It is respectfully pointed out that the citation referenced establishes that these groups are used to link the ligand to the support matrix but are not themselves pendant after linking. The disclosure goes on to state, "In this resin, the ligand is attached through a stable thioether bond." The subsequent examples, such as mercaptobenzimidazole, make it clear that the thiol is used to link the ionizable ligand (e.g. an imidazole moiety) to the support but is not the ionizable ligand itself.

It is agreed that hydroxyls and thiols could be ionizable ligands, but the disclosure does not provide a positive recitation of these groups as ionizable ligands.

Applicant's arguments filed 18 October 2002 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 112, first paragraph is adhered to for the reasons of record and the additional reasons above.

#### ***Claim Rejections - 35 USC § 102***

Claims 1-2, 4-5, 10-16, 18, 20 and 22-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Boardman et al. (1953).

The same arguments as raised in the response of 27 March 2002 are reiterated. It is asserted that the Declarations show that pH 6.1 is the pKa of the IRC-50 resin, so the resin is still 50% charged at this pH. It is asserted that the Declarations show that at pH 5.0 the resin retains a

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partial charge of 20%, which is greater than the "less than 5%" as required by the disclosure. It is urged that the experimental titration curve is more accurate than theoretical calculations of Henderson-Hasselbach. It is argued that Boardman fails to define "almost wholly undissociated." It is also argued that the rejection appears to rely upon Topp, Kunin, and Kitchener references and that the rejection should be under 103.

The most salient feature of Boardman, the titration curves shown in Figure 1, seems to have been overlooked. Clearly at pH 5.0, cytochrome C is bound, and elutes between pH values of 6-7 or 6-8 depending on ionic strength. Concomitantly, the resin takes up the sodium ions. Boardman also uses the resin to separate two carboxyhemoglobins with isoelectric points of 6.7 and 7.3 (Figure 2) at a pH of 5.8. The titration curve of the resin in the absence of protein may differ than with the protein. The arguments with respect to the Declarations have discussed in the Office action of 21 June 2002 and will not be restated. It is agreed that Boardman does not define the term "almost wholly undissociated", but taking its plain meaning suggests that the resin would meet the claim limitations. The Topp, Kunin, and Kitchener references were relied upon solely for their teachings of inherent properties, explanation of what the curves are showing, and for a larger figure of the titration curve of this resin. To assert that they are relied upon in an obvious type rejection is unwarranted.

Applicant's arguments filed 18 October 2002 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 102(b) is adhered to for the reasons of record and the additional reasons above.

*Claim Rejections - 35 USC § 103*

Claims 1-5, 7-23 and 55-56 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Boardman et al. (1953), Sasaki et al. (1979) and Sasaki et al. (1982) in view of Kunin (1958), Topp et al. (1949), Kitchener (1957) and Guthrie (1957) and further in view of Hancock et al. (US 4,401,629), Kitamura et al. (JP 01211543), Tokuyama (JP 60137441), Kondo et al. (JP 61033130), Iimuro et al. (US 4,950,807), Bruegger (US 4,810,391), Economy et al. (US 3,835,072), Jones et al. (US 4,154,676).

It is argued that the Board found that the Sasaki references do not obviate the instant claims because the references lack a resin that undergoes the transition between uncharged and charged between pH values of 5-9. It is urged that Sasaki references teach away because the resin they use suggests a pH value of 4.5 or less is necessary. It is urged that Sasaki references do not motivate substituting other resins. It is urged that Boardman teaches away too because it is only at "very low pHs" that the resin is fully charged. It is urged that the additional references teaching resins containing functional groups that may be ionizable fail to teach using these resins to purify proteins. Finally it is argued that combining fifteen references shows that the claimed invention is non-obvious.

The Board decision has been selectively interpreted. What the Board said is:

The examiner has asserted that "resins are known in the art which would be uncharged within the pH range of the scope of the claims." However, the examiner has not favored the record with any evidence in support of this assertion. As the record now stands, the prior art does not describe any resin which meets the requirements of the claims on appeal. In other words, the claimed resins are novel. If the examiner is aware of resins "known in the art which would be uncharged within the pH range of the scope of the claims," it is incumbent upon him to provide evidence in the record documenting the fact. The examiner has not done so.

It was solely on this basis that the rejection was not affirmed which is consistent with *In re Lee*, 61 USPQ2d 1430 (CAFC 2002). The Office action of 21 June 2002 provided the series of secondary references establishing the resins meeting the claim limitations were well known in the art. Specific examples of claimed functional groups pendant on the support were provided by these references. A large number of such references were cited to establish a large number of specifically recited functional groups. Hence, the record now clearly shows that such resins are well known in the art. It is not an assertion by the examiner as remarked by the Board. Further, the large number of references was provided solely for completeness. It was desirable to demonstrate that a large number of suitable functional groups were known in the art to be appended to supports.

Neither the Sasaki references nor Boardman teach away from the claimed invention. Sasaki provides a general concept and all of these three references merely provide specific examples. As is well known, the examples are non-limiting to the concept. They only provide working evidence of concept, unless there is some reason to believe the examples are the only possibility. In the instant case, the explanatory cartoon in Sasaki belies that suggestion. No specific pH values are given. Boardman is simply a specific example. They did not clearly contemplate the same concept as Sasaki.

Applicant's arguments filed 18 October 2002 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103(a) is adhered to for the reasons of record and the additional reasons above.

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*Conclusion*

No claims are allowed.

All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

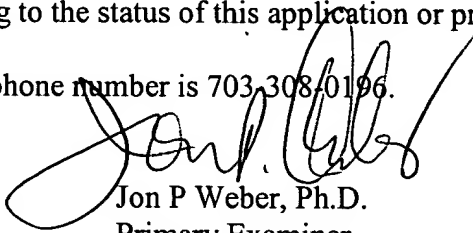
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
May 1, 2003